



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/476,275	06/07/95	ANDERSON	D 012712-155
			EXAMINER

18M1/0409

E. JOSEPH GESS
BURNS DOANE SWECKER & MATHIS
P O BOX 1404
ALEXANDRIA VA 22313-1404

SCHWADRON, R	
ART UNIT	PAPER NUMBER
1816	16

DATE MAILED: 04/09/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 12/20/96

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1, 2, 4, 5, 19-28 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 2, 4, 5, 19-28 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

15. Claims 1,2,4,5,19-28 are under consideration. Claims 19-21 have been amended.

RESPONSE TO APPLICANT'S ARGUMENTS

16. The amendment filed 12/20/96 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

The amendment to the specification, page 26, line 20 changes the scope of the disclosure which specifies the use of ALCONOX or MILLI-Q water, not any detergent or purified water. A preferred substitution is "washed with ALCONOX (a detergent) and rinsed with MILLI-Q water (purified water)".

Applicant is required to cancel the new matter in the response to this Office action.

17. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1,2,4,5,19-28 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 6-9 of copending application Serial No. 08/478967 for the reasons elaborated in paragraph 17 of the Office Action mailed 6/24/96. Applicant has indicated in the amendment filed 12/20/96 that a terminal disclaimer will be provided upon indication that the instant application is otherwise allowable.

19. Claims 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18 of copending application Serial No. 08/475,813 for the reasons elaborated in paragraph 18 of the Office Action mailed 6/24/96

Applicant has indicated in the amendment filed 3/21/96 that a terminal disclaimer will be submitted upon an indication that the claimed subject matter is otherwise allowable.

20. Regarding applicants comments about the Examiner's comments about the Reff declaration filed 1/4/96 the following comments are made. The error in the drawing with regards to the sequence should be corrected upon the filing of formal drawings.

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

22. Claims 19 and 20 remain rejected under 35 U.S.C. § 103 as being unpatentable over Grossbard in view of Anderson et al. for the reasons elaborated in paragraph 24 of the Office Action mailed 12/20/96. Applicants arguments in pages 6-14 of the amendment filed 12/20/96

have been considered and deemed not persuasive. Regarding the first Anderson declaration filed 12/20/96, said declaration does not address the issue of the contribution of inventors Leonard and Rastetter to the instant invention. Therefore the inventorship of the Anderson et al. publication as elucidated in the first Anderson declaration filed 12/20/96 still differs from the inventive entity of the instant invention. Regarding applicants comments on pages 7-14 of the instant amendment, in view of the fact that a variety of different murine antiCD20 antibodies had been used for the treatment of B cell lymphoma, it would have been obvious to a routineer that any chimeric antiCD20 antibody could have been used for treating B cell lymphomas based on the art known advantages of chimeric over murine antibodies. Furthermore, the art recognized that chimeric antiCD20 antibodies could be used for the treatment of human disease (eg. see Robinson et al, WO 88/04936, page 29, first complete paragraph). A routineer would have used a chimeric antibody in combination with a radiolabelled murine antibody because Grossbard et al. teach that radiolabelled chimeric antibodies would be therapeutically inferior to radiolabelled murine antibodies because "prolonged serum half-life of humanized RAbs may result in a substantial increase in nonspecific total body irradiation." (page 873, first column, last paragraph). Regarding applicants comments on pages 7-14 of the instant amendment, Table 6 of Grossbard demonstrates that a variety of different antiCD20 antibodies have already been used successfully for the treatment of human disease. Regarding the IDEC press release submitted with the instant amendment, Grossbard et al. teach that similar results were achieved in clinical trials using radiolabelled antiCD20 murine antibody (see Table 6, first column). Regarding applicants comments on pages 11-14 of the instant amendment, the Anderson declaration submitted 3/21/96 seems to indicate that the claimed chimeric antibody was not available other than to the authors of the Anderson et al. publication. However, the M.P.E.P. in section 2132, part (c) (2100-47, Rev. 1, Sept. 1995) indicates that the "by others" clause of 35 U.S.C. § 102(a) means "any combination of authors or inventors different than the inventive entity".

23. Claims 1,2,4,5,21-28 stand rejected under 35 U.S.C. § 103 as being unpatentable over Robinson et al. (WO 88/04936) in view of Anderson et al. for the reasons elaborated in paragraph 25 of the Office Action mailed 6/24/96. Applicants arguments in page 15 of the amendment filed 12/20/96 have been considered and deemed not persuasive. Regarding the first

Anderson declaration filed 12/20/96, said declaration does not address the issue of the contribution of inventors Leonard and Rastetter to the instant invention. Therefore the inventorship of the Anderson et al. publication as elucidated in the first Anderson declaration filed 12/20/96 still differs from the inventive entity of the instant invention.

24. The rejection of claims 1,2,4,5,21-28 under 35 U.S.C. § 103 as being unpatentable over Robinson et al. (US Patent 5,500,362) is withdrawn in view of the second Anderson declaration filed 12/20/96.

25. The rejection of claims 1,2,4,5,21-28 under 35 U.S.C. § 103 as being unpatentable over Robinson et al. (WO 88/04936) is withdrawn in view of the second Anderson declaration filed 12/20/96.

26. The rejection of claims 19 and 20 under 35 U.S.C. § 103 as being unpatentable over Robinson et al. (US Patent 5,500,362) or Robinson et al. (WO 88/04936) as applied to claims 1,2,4,5,21-28 above and further in view of Grossbard et al. is withdrawn in view of the second Anderson declaration filed 12/20/96.

27. No claim is allowed.

28. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Art Unit 1816

29. Papers related to this application may be submitted to Group 180 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 180 at (703) 305-7939.

30. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Tuesday through Friday from 8:30 to 6:00.

The examiner can also be reached on alternative Mondays. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Ms Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 180 receptionist whose telephone number is (703) 308-0196.



RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP 1800

Ron Schwadron, Ph.D.

Primary Examiner

Art Unit 1816

April 8, 1997